CLAIMS

WE CLAIM:

1. A kit comprising an oligonucleotide detection assay configured for detecting the number of CYP2D6 gene copies present in a sample and configured to identify the presence or absence of at least two CYP2D6 associated polymorphisms.

2. The kit of Claim 1, wherein said detection assay comprises an invasive cleavage assay.

3. The kit of Claim 1, wherein said detection assay is configured to detect the copy of number of the CYP2D6 gene and, separately, the copy number of a least one portion of the CYP2D6 gene.

4. The kit of Claim 1, wherein said CYP2D6 associated polymorphisms are selected from the group consisting of 19G>A, 31G>A, 100C>T, 124G>A, 221C>A, 833G>C, 984A>G, 1023C>T, 1039C>T, 1661G>C, 1707T>del, 1758G>A, 1758G>T, 1846G>A, 1863ins[TTTCGCCCC]2, 1943G>A, 1973insG, 2539-2542delAACT, 2549A>del, 2613-2615delAGA, 2850C>T, 2935A>C, 3183G>A, 3259insGT, 3853G>A, 3887T>C, 4042G>A, 4180G>C, gene copy number, copy number 31G, copy number 100T, and copy number 4180G.

5. The kit of Claim 1, further comprising a control reagent for assessing CYP2D6 copy number.

6. The kit of Claim 5, wherein said control reagent comprises reagents for detection of alpha-actin.

7. The kit of Claim 5, wherein said control reagent comprises synthetic target nucleic acids having 0, 1, 2, 3, or 4 copies of a CYP2D6 gene sequence.

8. The kit of Claim 1, wherein said detection assay is configured to detect the copy number of at least one of said polymorphisms.

9. The kit of Claim 1, wherein said polymorphisms are selected from the group consisting of 31G>A, 100C>T, and 4180 G>C.

10. The kit of Claim 5, wherein said control reagent comprises synthetic target nucleic acids having 0, 1, 2, 3, or 4 copies of a mutant CYP2D6 sequence.

11. A method for detecting a CYP2D6 genotype of a sample, comprising:

a) providing:

i) a sample comprising a target nucleic acid;

ii) a detection assay configured to detect at least two CYP2D6 polymorphic sequences and to detect CYP2D6 copy number;

b) exposing said sample to said detection assay under conditions such that said at least two CYP2D6 polymorphic sequences are detected and CYP2D6 copy number is detected, thereby detecting a CYP2D6 genotype of said sample.

12. The method of Claim 11, wherein said detection assay comprises an invasive cleavage assay.

13. The method of Claim 11, wherein said target nucleic acid is amplified prior to said exposure step.

14. The method of Claim 11, wherein said detection assay is configured to detect the copy of number of the CYP2D6 gene and, separately, the copy number of a least one portion of the CYP2D6 gene.

15. The method of Claim 11, wherein said CYP2D6 polymorphic sequences are selected from the group consisting of 19G>A, 31G>A, 100C>T, 124G>A, 221C>A, 833G>C, 984A>G, 1023C>T, 1039C>T, 1661G>C, 1707T>del, 1758G>A, 1758G>T, 1846G>A, 1863ins[TTTCGCCCC]2, 1943G>A, 1973insG, 2539-2542delAACT, 2549A>del, 2613-2615delAGA, 2850C>T, 2935A>C, 3183G>A, 3259insGT, 3853G>A, 3887T>C, 4042G>A, 4180G>C., gene copy number, copy number 31G, copy number 100T, and copy number 4180G.

16. The method of Claim 11, wherein said detection assay further detects a copy number of at least one of said polymorphic sequences.

17. The method of Claim 11, wherein said polymorphic sequences are selected from the group consisting of 31G>A, 100C>T, and 4180 G>C.

18. A method for genotyping a subject having a CYP2D6 gene comprising the steps of:

a) detecting at least 25 single nucleotide polymorphisms associated with the CYP2D6 gene in said subject;

b) detecting the CYP2D6 gene copy number;

c) if multi-copy number polymorphisms are present, detecting the copy number of said multi-copy number polymorphism; and

d) generating a genotype profile based on the information derived from steps a-c; and

e) comparing said genotype profile to a predetermined CYP2D6 information matrix, such that a CYP2D6 genotype of said subject is determined.

19. The method of Claim 18, wherein said single nucleotide polymorphisms and said information matrix is selected such that over 99% of Caucasian ultra metabolizers and over 95% of intermediate and low metabolizer are genotyped for CYP2D6.

20. The method of Claim 18, wherein said 25 polymorphisms are selected from the group consisting of 19G>A, 31G>A, 100C>T, 124G>A, 221C>A, 833G>C, 984A>G, 1023C>T, 1039C>T, 1661G>C, 1707T>del, 1758G>A, 1758G>T, 1846G>A, 1863ins[TTTCGCCCC]2, 1943G>A, 1973insG, 2539-2542delAACT, 2549A>del, 2613-2615delAGA, 2850C>T, 2935A>C, 3183G>A, 3259insGT, 3853G>A, 3887T>C, 4042G>A, 4180G>C, gene copy number, copy number 31G, copy number 100T, and copy number 4180G.

21. The method of Claim 18, wherein said multi-copy number polymorphisms are selected from the group consisting of 31G>A, 100C>T, and 4180 G>C.

22. The method of Claim 18, wherein said predetermined CYP2D6 information matrix is stored in a computer memory.

23. The method of Claim 18, further comprising the step of using said CYP2D6 genotype in selecting a therapy for a subject.

24. The method of Claim 18, further comprising the step of comparing said CYP2D6 genotype to a drug interaction observed in said subject.